

REMARKS

Claims 1, 7-10, 14-20, 26-32, 38-40, and are pending.

The issues outstanding in this application are as follows:

- Claims 1, 7-10, 14-19, 26-32 and 38-40 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Van Bree et al. (WO 01/72322).
- Claims 1, 7, 14, 17-19, 26-32 and 38-40 are provisionally rejected on the basis of nonstatutory double patenting.

I. 35 U.S.C. §103(a)

Claims 1, 7-10, 14-19, 26-32 and 38-40 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Van Bree et al. (WO 01/72322).

To establish a *prima facie* case for obviousness, all claim limitations must be accounted for. The Examiner maintains the rejection on the below reasoning:

While Van Bree teaches intravenous administration of lactoferrin at high dosages for bacteremia, the reference also teaches oral formulations of lactoferrin and the use of the oral formulation in the treatment of infections of the digestive tract (page 26, line 22+), thus the reference suggests oral administration of the N-terminal lactoferrin variants in the treatment of bacterial infection or sepsis, and which was, as a whole, *prima facie* obvious at the time the claimed invention was made.

Pg. 5 of the pending office action.

Applicant respectfully submits that the Examiner's analysis is misplaced due to a error in claim construction. It is clear from the above reasoning that the Examiner has equated the claim term "sepsis" (and implicitly "bacteremia") with any bacterial infection.

Consequently, the Examiner has cited the teaching of Van Bree regarding oral Lactoferrin therapy for digestive tract infections as a pertinent disclosure. Applicant's Specification clearly defines bacteremia [0032] and sepsis [0050]:

[0032] The term "bacteremia" as used herein is defined as having a focus of bacterial infection or bacteria in the blood of the subject.

[0050] The term "sepsis" as used herein is defined as a Systemic Inflammatory Response Syndrome to an infective process in which severe derangement of the host immune system fails to prevent extensive `spill over` of inflammatory mediators from a local infection focus into the systemic circulation.

These terms, and thus the claimed methods, do not encompass the digestive tract infections referred to in Van Bree as amenable to oral Lactoferrin treatments. MPEP 2111.01 (IV. APPLICANT MAY BE OWN LEXICOGRAPHER).

Van Bree teaches oral formulations of Lactoferrin. Pg. 26-27. However, Van Bree also teaches that the "particular form of the composition varies with the intended mode of administration and therapeutic application." There is no suggestion or teaching to use oral lactoferrin in the treatment of bacteremia [0032] or sepsis [0050]. On the contrary, Van Bree teaches intravenous administration of lactoferrin at high dosages for bacteremia. Pg. 3 and Examples; Pg. 22 lines 7-12. This intravenous administration is used to introduce Lactoferrin systemically to directly bind and thereby neutralize and accelerate clearance of LPS. *Id.* at pg. 3, lines 22-24. In contrast, orally administered Lactoferrin is not systemically bioavailable and thus oral administration cannot be seen as an obvious alternative to the systemic administration disclosed by Van Bree. *See* Kuhara et al, "Orally Administered Lactoferrin Exerts an Antimetastatic Effect and Enhances Production of IL-18 in the Intestinal Epithelium," *Nutrition and Cancer*, Vol 28 No 2, 2000, pp. 192-199 at pg. 192, lines 8-10. Taken as a whole, Van Bree cannot be fairly viewed as teaching or suggesting oral administration for bacteremia [0032] or sepsis [0050]. *KSR International Co. v. Teleflex, Inc.*, 550 U.S.____ (2007) (No. 04-1350, decided April 30, 2007, at pg. 14) ("[R]ejections

on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," quoting *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006))

Applicant respectfully requests that the rejection be withdrawn.

II. Provisional Double Patenting over 10/663,258

A "provisional rejection" is unlike a regular rejection in that it is contingent upon an event unrelated to the prosecution of the present application that may never come to pass, while a regular rejection is made in view of facts actually in existence at the time the rejection is made. A provisional double-patenting rejection is based on the claims of a co-pending application as originally filed. Because the co-pending application may never actually issue, or, alternatively, the claims as originally filed may be amended during the course of prosecution of the co-pending application such that the claims, when issued, no longer impact Applicants' claims, the rejection remains "provisional" until the co-pending application issues. If the issued application still results in a double-patenting rejection, the provisional status of the rejection is removed, and the rejection becomes a regular double-patenting rejection. Once the rejection is made non-provisional, Applicants are then able to address fully the double-patenting concerns with regard to the substance of the claims that have actually issued in the referenced patent. The Office and Applicants are saved from needless speculation as to whether the co-pending application will actually issue or what the substance of the final issued claims will be. As such, Applicants are not required to address the merits of the provisional double-patenting rejections until such time as the co-pending applications actually issue.

Indeed, while M.P.E.P. § 804 allows for the merits of the rejection to be addressed while the rejection remains provisional ("[t]he merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue"), the Court of Claims and Patent Appeals (now the Court of Appeals for the Federal Circuit) has stated: "Once the provisional rejection has been made, there is nothing the examiner and the applicant must do until the other application issues." *In re Mott*, 190

U.S.P.Q. 536, 541 (C.C.P.A. 1976) (emphasis added). M.P.E.P. § 804 allows for the prosecution to continue while a provisional double-patenting rejection is pending and even instructs the Office to continue to make such a provisional rejection until one of the applications issues as a patent. For example, M.P.E.P. § 804 states:

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent."

Applicants further submit that it is proper for the Office to continue prosecution in light of the provisional status of the rejections and to allow Applicants to address the merits of the double-patenting rejection at such time as the co-pending application(s) actually issue.

The courts have endorsed the appropriateness of the Office allowing the provisional rejection to remain standing during prosecution until the co-pending application actually issues. For example, in *In re Wetterau*, 148 U.S.P.Q. 499 (C.C.P.A. 1966), the Court of Customs and Patent Appeals held that a provisional double-patenting rejection in view of a co-pending application was proper. Even though the claims of the co-pending application had already been allowed, the court stated, "no assurance can be given that the status will endure and a patent containing such claims will ultimately issue." 148 U.S.P.Q. at 501. The court found the uncertainty of the co-pending application's status was sufficient to allow the provisional rejection to remain standing and to prevent the applicant from having to abandon the case. In holding such, the court stated:

If a patent were not to issue on the Carabateas [co-pending] application, the "double patenting" rejection, if here affirmed, would of necessity evaporate for the possibility of two patents would not exist. Grave injury to applicant's rights might occur if the Wetterau [applicant's] application were to go abandoned

through no fault of the applicant prior to the issuance of Carabateas, the reference application.

Id.

In view of the above, Applicants submit that they have acknowledged the provisional double-patenting rejections and, further, that it is clear Applicants are not required to address the merits of the provisional double-patenting rejections until such time as the co-pending application(s) issue and the rejections are made non-provisional.

In view of the above, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02703US2 from which the undersigned is authorized to draw.

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Respectfully submitted,

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